REMARKS

Status of the Claims

Claims 1-6, 8-14 and 16-23 are currently pending in the application and stand rejected. Claim 1 has been amended. Support for this amendment can be filed in the originally filed specification and claims, e.g., dependent claim 8 as well as page 5, line 31; page 6, lines 21-25 and 28-30; page 7, lines 1-3 of the specification.

New claim 23 has been added. Support for this new claim can be found in the originally filed specification and claims, e.g., claim 1 and page 6, line 6. Applicants believe that the proviso now recited in claim 23 is fully supported by the specification as filed. Applicants are simply claiming less than the full scope of their disclosure—a perfectly legitimate exercise since it is for the inventors to decide what bounds of protection they will seek. Moreover, Applicants respectfully submit that *In re Johnson*, 194 USPQ 187 (C.C.P.A. 1977) provides legal precedent allowing the addition of these provisos.

The facts of the present case are analogous to the facts of *Johnson*. In *Johnson* and in the present case, a broad and generic disclosure of the excluded components is set forth: In *Johnson*, a broad class of precursor compounds with specific examples was disclosed; in the present specification, a Markush class of pharmaceutically acceptable oils with specific examples is disclosed. Based on these common underlying factors, Applicants respectfully submit that *Johnson* is analogous to the present case.

The holding in *Johnson* is not limited to permitting only the exclusion of compounds which have been specifically recited in the specification. Rather, *Johnson*

requires that a "broad and complete generic disclosure, coupled with extensive examples fully supportive of the limited genus now claimed" must be present to support the exclusion of specific compounds. *In re Johnson*, 194 USPQ at 196.

Applicants respectfully submit that a broad and complete generic disclosure coupled with extensive examples fully supportive of the limited genus now claimed is set forth in this application. Part of the broad generic disclosure begins on page 5 line 27, and continues through page 7, line 6. Examples of possible pharmaceutically acceptable oils for use in the inventive compositions and methods appear on page 6, lines 1-25. Thus, the specification and claims as originally filed set forth specific compounds that are not excluded by the new proviso recited in claim 23. As in *Johnson*, this fact provides sufficient evidence that Applicants considered the subject matter of the presently claimed invention to be within the scope of their invention, and the new proviso is not new matter for this reason alone.

Moreover, adequate written description, particularly with respect to provisos, does not require literal support for the claimed invention. *In re Wertheim,* 191 USPQ 90, 98 (C.C.P.A. 1976). The originally filed disclosure provides support as long as it would have reasonably conveyed to one having ordinary skill in the art that an applicant had possession of the concept of what is now claimed. *In re Anderson*, 176 USPQ 331, 336 (C.C.P.A. 1973).

One case often cited by the U.S. Patent and Trademark Office in response to an amendment limiting the scope of a claim in view of prior art differs from the present situation. In *Ex parte Grasselli*, 231 USPQ 393, 394 (Bd. Pat. App. 1983), the claim at issue related to a process for the ammoxidation of propane or isobutane comprising

using a catalyst described by a certain formula. During prosecution, the claim was amended to recite that the catalyst was free of uranium and from the combination of vanadium and phosphorus. The formula, however, did not originally cover uranium. Thus, the applicant sought to exclude uranium from the catalyst, but a uranium-containing catalyst was not a species falling within the genus of the original catalytic formula. The applicant urged that the catalyst recited in the claims was open to inclusion of all other elements not expressly excluded by the negative limitation. The Board held that there was no written description for the negative limitation.

The *Grasselli* facts sharply contrast with the present facts. In *Grasselli*, uranium was never covered by the original genus. In the present case, Applicants seek nothing more than to exclude by proviso certain species of compositions, all of which fall within the genus of compositions originally described.

While *Grasselli* is not applicable, the rationale of *Wertheim* approaches the present situation more closely. *See In re Wertheim*, 191 USPQ 90 (C.C.P.A. 1976). In *Wertheim*, the C.C.P.A. cautioned against letting form triumph over substance by eliminating the right of an applicant to retreat to an otherwise patentable species merely because the applicant mistakenly thought he was the first to invent the broad genus at the time he filed his application. *See In re Wertheim*, 191 USPQ at 97. The present situation, like that in *Wertheim*, does not involve the introduction of a new concept such as that forbidden by *Grasselli*. Rather, the present situation involves a retreat to species within the originally claimed genus. *Wertheim* approved that approach, and the Office has no reason to treat Applicants under any other standard.

Additionally, as the Board of Patent Appeals & Interferences stated in *Ex parte Parks*, 30 USPQ2d 1234, 1236 (BPAI 1994), the decision in *Grasselli* involved claims that contained a negative limitation that introduced new concepts in violation of 35 U.S.C. § 112, first paragraph. *Parks* was like *Grasselli* in that the claim recited a negative limitation, specifically "in the absence of a catalyst." The proviso in *Parks* did not involve a situation where a species/subgenus of an original genus constituted the subject matter of the proviso. Nonetheless, the Board in *Parks* found written description support, proving that *Grasselli* must be carefully applied only to cases where amendments introduce a new concept into the application.

Finally, Applicants respectfully submit that the specification as filed would also be fully supportive of the species of compositions sought to be excluded by the proviso in claim 23. Peanut oil is found on page 6, line 6 of the specification. Because the specification discloses the ingredients that would have resulted in the excluded species of compositions, the excluded compositions would have been apparent to the skilled artisan after reading the specification as filed. Thus, the present specification would also be fully supportive of the species of compounds sought to be excluded by the proviso recited in new claim 23.

Accordingly, the proviso in claim 23 introduces no new concepts; it merely exclude species from the original genus. As explained above, *Grasselli* does not control the present situation, wherein Applicants utilize a proviso to exclude subject matter originally within the genus of the claim. Instead, *Wertheim* and *Johnson* control and therefore, no new matter has been added by this amendment. The relevant case law,

therefore, dictates that the provisos recited in claims 28, 65, and 84 find support in the specification.

Rejections Under 35 U.S.C. §103(a)

The test for determining if a claim is rendered obvious by one or more references for purposes of a rejection under 35 U.S.C. § 103 is set forth in *KSR International Co. v. Teleflex Inc.*, 550 U.S.398, 82 USPQ2d 1385 (2007):

> "Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." Quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966).

As set forth in MPEP 2143.03, to ascertain the differences between the prior art and the claims at issue, "[a]ll claim limitations must be considered" because "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385. According to the Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of *KSR International Co. v. Teleflex Inc.*, Federal Register, Vol. 72, No. 195, 57526, 57529 (October 10, 2007), once the *Graham* factual inquiries are resolved, there must be a determination of whether the claimed invention would have been obvious to one of ordinary skill in the art based on any one of the following proper rationales:

> (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for

another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try"—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. *KSR International Co. v. Teleflex Inc.*, 550 U.S.398, 82 USPQ2d 1385 (2007).

Furthermore, as set forth in *KSR International Co. v. Teleflex Inc.*, quoting from *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006), "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasonings with some rational underpinning to support the legal conclusion of obviousness."

Therefore, if the above-identified criteria and rationales are not met, then the cited reference(s) fails to render obvious the claimed invention and, thus, the claimed invention is distinguishable over the cited reference(s).

- Claims 1-4, 9-10, 12-14, 16 and 22 remained rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 4,999,198 to Barnett et al. (hereinafter "Barnett") in view of WO Patent No. 01/62214 to Zecchino et al. (hereinafter "Zecchino") as evidenced by Final report on the safety assessment of peanut (Arachis Hypogaea) oil etc., International Journal of Toxicology, 20(2):65-77, 2001. Applicants respectfully traverse the rejection for the reasons of record as well as those presented below.

As an initial matter, claim 1 has been amended to recite that the pharmaceutically acceptable oil comprises a mono-, di-, triglyceride, or mixtures thereof comprising C_6-C_{40} fatty acid chains, similar to the subject matter in non-rejected claim 8. Moreover, new claim 23 recites that the pharmaceutically acceptable oil is not peanut oil.

The Examiner relied upon Barnett for teaching a polyaphron comprising mineral or peanut oil as the disperse phase. In particular, Barnett teaches that the other oils used, i.e., almond, corn, and sesame, did not form stable polyaphrons. Col. 2, lines 12-15 and 33-36. Barnett discloses that the instability of the polyaphron systems could be attributed to the presence of fatty acids due to oxidation of the oils. Col. 2, lines 66-68. The oxidation could have been responsible for the neutralization of the surfactants and thus destroying some of the foam. Col. 2, line 68 to col. 3, line 4.

Based upon these results, the mineral and peanut oils were used to study the release rate of scopolamine into a water medium. Col. 2, lines 40-42. With the peanut oil, "no detectable release of scopolamine was observed after 68 hours." Col. 3, lines 8-10. Barnett teaches that because "scopolamine had an appreciable solubility in this oil, it ***didn't partition to any extent*** with water." Col. 3, lines 10-12 (emphasis added) and as acknowledged by the Examiner in the Final Office Action dated July 21, 2010 at 6. "Apparently peanut oil is ***unsatisfactory*** for this drug system." Col. 3, lines 14-15 (emphasis added).

Barnett does not teach or suggest the claimed invention because he does not teach or suggest, *inter alia*, a biliquid foam comprising a pharmaceutically acceptable oil, wherein the pharmaceutically acceptable oil is a mono-, di-, or triglyceride, or a

mixture thereof. To be clear, Barnett clearly teaches that using an oil, such as peanut oil, is "unsatisfactory." One of ordinary skill in the art reading Barnett would not have been motivated to use the claimed oil, or for that matter any oil except for mineral oil, because mineral oil was the only oil providing stability and release of the drug into the water medium. In fact, Barnett teaches away from the using the claimed oil because not only did peanut oil not release the drug, but also because Barnett teaches that oils oxidize leading to fatty acids which neutralize the surfactants and thus destroy the foam of the polyaphron. For at least these reasons, one of ordinary skill in the art reading Barnett would not have been motivated to use the claimed oil in a polyaphron system because Barnett clearly teaches away from using the claimed oil. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)

The Examiner also admits that Barnett does not teach or suggest the amount of continuous phase and surfactant in its polyaphron systems.

The Examiner relied upon Zecchino for teaching the amount of continuous phase and surfactant and argued that it would have been obvious to incorporate the hydrophilic phase and surfactant amounts of Zecchino into the polyaphron of Barnett because both references teach an aqueous medium and a surfactant. Final Office action dated November 25, 2009 at 6. However, Zecchino does not overcome the deficiencies discussed above with regard to Barnett. Zecchino teaches that the oil phase of the foam can be composed of any type of oil, such as, e.g., vegetable oils, such as corn oil. However, one of ordinary skill in the art would not have been motivated to use the vegetable oils, such as the corn oil of Zecchino, in the polyaphron

system of Barnett because Barnett teaches that only mineral oil is acceptable for use in a polyaphron system. In particular, Barnett teaches that the corn oil of Zecchino is not suitable for use in a polyaphron system because it was not stable "for any significant period of time." So, one of ordinary skill in the art reading the list of suitable oils in Zecchino would know from reading Barnett that not all oils work in a polyaphron system. In particular, some oils do not provide a stable polyaphron system and other oils do not release a drug. So, while one of ordinary skill in the art reading Zecchino may think that all the oils listed would work in a polyaphron system, Barnett teaches that that rationale is flawed, for at least the reasons disclosed in Barnett.

Moreover, using the oils disclosed in Zecchino, such as the corn oil, in the polyaphron of Barnett would render it inoperable for its intended purpose. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). For at least these reasons, one of ordinary skill in the art would not have been motivated to combine the teachings of Barnett and Zecchino with a reasonable expectation of successfully achieving the claimed invention.

The Examiner argued that the phrase "oral drug delivery system" was merely intended use. Final Office Action dated November 29, 2009 at 7. The Examiner argued that a recitation of the intended use of the claimed invention must result in a structural difference in order to patentably distinguish the claimed invention. *Id.* The Examiner argued that "[i]f the prior art structure is capable of performing the intended use, then it meets the claim." *Id.* To be clear,

Zecchino's composition is not an oral drug delivery system and is not capable of performing the intended use and therefore does not meet the claim limitation. The polyaphron system of Zecchino is directed to polyaphrons that deliver salt or electrolytic active materials to the skin in a convenient or aesthetically pleasing manner. Page 2, lines 17-20.

The effect of preamble language should be resolved based on a review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim. *See, e.g., Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). The prosecution history is a factor relevant to the determination of the weight a preamble should be given as a claim limitation. For example, if the prosecution history contains evidence that the preamble was treated as a feature distinguishing the claimed invention from the prior art, a court may find that the preamble is a claim limitation. *See, e.g., Phillips Petroleum Company, v. Huntsman Polymers Corporation,* 157 F.3d 866, 873 (Fed. Cir. 1998). *See also Middleton, Inc., v. Minnesota Mining & Manufacturing Company*, 311 F.3d 1384 (Fed. Cir. 2002) (where the applicant's arguments during prosecution that distinguished the claimed invention from the prior art based on features of the preamble were found to support a conclusion that the preamble was a claim limitation). Like in *Middleton*, Appellant has argued throughout the prosecution that the preamble is a claim limitation not taught or suggested by the cited references. Applicant has argued that Zecchino does not teach or suggest an

oral drug delivery system. In particular, materials that can be used for skin delivery and cosmetic product are not necessarily suitable for oral or food use unless they have been registered. Toxicity is an extreme category of suitability for oral use. A great deal of materials that are not toxic cannot be used for oral consumption because they have not been approved by the federal regulatory agency. Approval of materials for oral use requires testing, rigorous analysis and extensive paperwork to ensure there are no side-effects. For example, Zecchino requires the use of polymeric sulfphonic acids which are not suitable for oral consumption. While compounds may be non-toxic for topical use, they would be considered toxic for oral consumption. *See Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808-09 (Fed. Cir. 2002) ("[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." Consequently, "preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant."). As shown in the prosecution history, Applicant has relied on the preamble, "on oral drug delivery system," during prosecution to distinguish the claimed invention from the prior art thus treating the preamble as a claim limitation.

Further, the Court has held in several cases that the "for use" preamble language has been recognized as providing essential limitations to the claims.

See also, e.g., Bass Pro Trademarks v. Cabela's, 485 F.3d 1364 (Fed. Cir. 2007) (holding that a preamble may be limiting when the prosecution history indicates that the Applicant distinguished cited art on the basis of the citation in the preamble.); *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006) ("[W]hether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent."); *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) ("The effect preamble language should be given can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); *In re Stencel*, 828 F.2d 751, 754 (Fed. Cir. 1987) ("Whether a preamble of intended purpose constitutes a limitation to the claims is, as has long been established, a matter to be determined on the facts of each case in view of the claimed invention as a whole.").

Moreover, if the preamble is not given any patentable weight, then the claim would be directed to all biliquid foams, which is not what Applicant regards as his invention. Clearly, the additional recitation of the "pharmaceutically acceptable oil" and "unit dosage form" in the claims further establishes that the claim is directed to an oral drug delivery system and not to all biliquid foams. In fact, the term "oral drug delivery system" gives life and meaning to the claims. *See, e.g., General Elec. Co. v. Nintendo Co.*, 179 F.3d 1350, 1361-62 (Fed. Cir. 1999) (the preamble phrase "raster scan display device" limited a method for displaying computer generated information on a screen,

because "[i]n light of the specification, to read the claim indiscriminately to cover all types of display systems would be divorced from reality"); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 678 (Fed. Cir. 1988) (the phrase "a base for the support of equipment" was essential in giving meaning to the invention and therefore was limiting, and precluded a finding of anticipation); *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 896 (Fed. Cir. 1984) ("The system of claim 1 is one of unity magnification and is image forming. Those limitations appear in the preamble, but are necessary to give meaning to the claim and properly define the invention.")

Further, the Examiner argued a number of times that the Applicant was attacking the references individually. This is not true. Applicants have been citing to various passages of the references to show that no motivation exists to combine the reference teachings as proposed by the Examiner. For example, Barnett only teaches topical solutions (col. 1, lines 38-39) and Zecchino only teaches topical cosmetic compositions. Therefore, one of ordinary skill in the art would not have been motivated to combine the two teachings with a reasonable expectation of arriving at the claimed invention, i.e, an oral drug delivery system.

Moreover, as discussed above, Barnett teaches away from the claimed invention, i.e., he teaches that a mono-, di- or triglyceride oil is not stable, and does not release a drug, and is therefore unsatisfactory for use in a drug delivery system. Zecchino teaches that any oil will work in a polyaphron system. One of ordinary skill in the art reading Barnett would know that the teachings of Zecchino are not correct and would not be motivated to use just any oil as taught by Zecchino. Moreover, as discussed above, it is improper to combine references that teach away from the claimed invention,

and it is improper to combine references that would render them operable for their intended use.

For at least the foregoing reasons, the references, alone or in combination, fail to render obvious the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

- Claims 1, 5-6 and 8 remained rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Barnett in view of Zecchino and WO Patent No. 97/332559 to Wheeler et al. (hereinafter "Wheeler"). Applicants respectfully traverse the rejection for the reasons already of record as well as those presented below.

As discussed above, Barnett teaches away from the claimed invention. Moreover, one of ordinary skill in the art would not have been motivated to modify Barnett by using the amounts of surfactant and water of Zecchino to arrive at the claimed invention with any reasonable expectation of success. In particular, Zecchino teaches that any oil can be used in the polyaphron system, when this is directly contradicted by the teachings of Barnett, which teaches that the claimed pharmaceutically acceptable oils would not result in a stable polyaphron system and would not release a drug dispersed in the oil.

The Examiner relied upon Wheeler for teaching a biliquid foam suitable for use in pharmaceutical and other industries. Abstract and Office Action dated January 22, 2009 at 6. Moreover, the Examiner asserted that Wheeler discloses the incorporation of an alcohol or other acceptable water soluble materials in the hydrophilic phase, which are examples of hydrophilic non-aqueous solvents. In particular, the Examiner notes

that Wheeler teaches caprylic/capric triglyceride having a carbon chain length of 8-10 carbons as an acceptable oil. However, there is no motivation to combine the teachings of Wheeler with those of Barnett and Zecchino with a reasonable expectation of success of arriving at the claimed invention.

As discussed above, Barnett, Zecchino and Wheeler are all directed to topical polyaphron systems. None of the references teach or suggest an oral drug delivery system as claimed. Moreover, one of ordinary skill in the art would understand that not all chemical compounds suitable for topical use can be used in oral systems because they may be toxic and/or not federally approved. Thus, absent a specific teaching or suggestion in the references that the polyaphrons disclosed in Barnett, Zecchino and/or Wheeler could be used in an oral drug delivery system one of ordinary skill in the art would not have modified any of the disclosed compositions for oral use.

For at least the foregoing reason, the references, alone or in combination, fail to render obvious the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

- Claims 1 and 10-11 remained rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Barnett in view Zecchino and U.S. Patent No. 6,599,527 to Leigh et al. (hereinafter "Leigh"). Applicants respectfully traverse the rejection for the reasons already of record as well as those presented below. As discussed above, claim 1 has been amended to recite that the pharmaceutically acceptable oil comprises a mono-, di-, triglyceride, or mixtures thereof comprising C_6-C_{40} fatty acid chains, similar to the subject matter in non-rejected claim 8.

Barnett and Zecchino have been discussed at length above.

The Examiner relied upon Leigh for teaching a pharmaceutical composition for the improved absorption of lipophilic drugs which comprises phospholipids such as phosphatidycholine and mono-acyl phosphatidyl choline. Abstract and Office Action dated January 22, 2009. It would not have been prima facie obvious to substitute emulsifiers because the incorporation of phospholipids enchances the absorption of and bioavailability of lipophilic drugs. However, there is no motivation to combine the teachings of Leigh with those of Barnett and Zecchino with a reasonable expectation of success of arriving at the claimed invention.

As discussed above, Barnett teaches away from the claimed invention and Zecchino teaches that any oil can be used, which is not true according to the teachings of Barnett. Leigh does not provide any teachings or suggestions to one of ordinary skill in the art that would motivate one to modify Barnett and/or Zecchino to use the claimed pharmaceutically acceptable oil.

For at least the foregoing reason, the references, alone or in combination, fail to render obvious the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

- Claims 1 and 17-21 remained rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Barnett in view Zecchino and U.S. Patent No. 5,952,383 to Metziger et al. (hereinafter "Metziger"). Applicants respectfully traverse the rejection for the reasons already of record as well as those presented below. As discussed above, claim 1 has been amended to recite that the pharmaceutically acceptable oil comprises

a mono-, di-, triglyceride, or mixtures thereof comprising C_6-C_{40} fatty acid chains, similar to the subject matter in non-rejected claim 8.

Barnett and Zecchino have been discussed at length above.

The Examiner relied upon Metziger for teaching a pharmaceutical composition for oral administration containing a medical product that is insoluble or sparingly soluble. Abstract and Office Action dated January 22, 2009 at 7. The composition of Metziger comprises an oil such as a triglyceride of 8-12 carbon atoms and a surfactant such as a nonionic surfactant. Citing claims 1, 2, and 5 of Metziger. The Metziger composition can be formed into soft or hard gelatin capsules. Citing claims 9 and 11 of Metziger. The Examiner argued that one of ordinary skill in the art would have been motivated to incorporate the composition into a capsule because capsules are known and Metziger teaches compositions containing poorly water-soluble drugs. However, there is no motivation to combine the teachings of Metziger with those of Barnett and Zecchino with a reasonable expectation of success of arriving at the claimed invention.

As discussed above, Barnett teaches away from the claimed invention and Zecchino teaches that any oil can be used, which is not true according to the teachings of Barnett. Metziger does not provide any teachings or suggestions to one of ordinary skill in the art that would motivate one to modify Barnett and/or Zecchino to use the claimed pharmaceutically acceptable oil.

For at least the foregoing reason, the references, alone or in combination, fail to render obvious the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims. This is believed to be a complete and proper response to the Examiner's Office Action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 50-3290.

Respectfully submitted,

Dated: January 21, 2011

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